IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff,

v.

ACCORD HEALTHCARE INC., et al.,

Defendants.

PUBLIC VERSION FILED: MAY 22, 2019

C.A. No. 18-1043-LPS

[redacted]

REPLY BRIEF
IN SUPPORT OF NOVARTIS'S MOTION
FOR A PRELIMINARY INJUNCTION

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PRELIMINARY STATEMENT

Infringement is not disputed. Nor is the Patent Office's conclusion in the IPR that the prior art taught away from the invention. The 405 Patent thus claims a true scientific advance.

Defendants nonetheless oppose a preliminary injunction. Defendants argue the Patent is anticipated by "Kappos 2006," a short abstract reporting an upcoming Phase III clinical trial. But other reports of that upcoming trial were already part of the IPR, and the Patent was still found valid. The Patent claims a method to treat RRMS with a daily dose of 0.5 mg of fingolimod, whereas Kappos 2006 merely summarizes the trial design for testing fingolimod doses against placebo in human MS. The 0.5 mg dose had never before been tested in human MS, and it was unknown whether or not it would have any effect. A test is not a treatment. Defendants' MS physician expert Dr. Hoffman even admitted that he would not administer 0.5 mg to his patients before the trial because he "wouldn't know whether [the 0.5 mg dose] was effective or not." That, among other things below, disposes of anticipation.

Through the eyes of an MS physician alone, Defendants next say the Patent neither enables nor properly describes the invention. But the Patent Office found that the person of skill is a team that includes a pharmacologist too. Dr. Hoffman admits a pharmacologist is needed to understand the link between the Patent's animal data and the claimed dose. Unrebutted expert pharmacology testimony from Novartis confirms this point.

Defendants have abandoned any other invalidity theories. Irreparable injury would follow from a launch at risk. Gilenya is a flagship product with annual U.S. sales of $1.8 billion. A launch would crash prices, deflate market share, [redacted], and otherwise inflict incalculable harm on Novartis and patients. Novartis asks the Court to prevent that result.

ARGUMENT

I. Novartis Is Likely To Succeed on the Merits

The IPR result alone shows a likelihood of success on validity.[1] (Nov. Br. at 13–14.) The Patent Office has already found the Patent valid over a vigorous challenge. Courts weigh prior validity findings heavily in a later preliminary injunction, even when different references are involved.[2] The prior dispute is assumed to have "animated . . . search[es] for the best prior art[.]" *Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1579 (Fed. Cir. 1983). New references in the second case are likely cumulative or too weak to have been in the first case.

So it is here—Kappos 2006 is both, and may not be prior.[3] It is merely one of several announcements of the upcoming Phase III trials. Two others were in the IPR. (Nov. Br. at 9–10, 14 n. 5.) All say 0.5 mg daily would be tested in RRMS. (*Id*. at 13–14.) Defendants'

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[1] Defendants (at 1) assert "Novartis must clearly show that it will succeed in proving the patent-in-suit valid." Novartis has no burden to "prove" the Patent "valid." The law presumes the Patent valid. (*See* Nov. Br. at 12–13.) That presumption applies here. *See, e.g.*, *Tinnus Enterprises, LLC v. Telebrands Corporation*, 846 F.3d 1190, 1205 (Fed. Cir. 2017) (presumption of validity alone enough "to establish a likelihood of success").

Defendants say also (at 8) they need only raise a "substantial question" of validity to defeat this motion. But a "substantial question" of validity is just a "substantive conclusion" based on the "net of the evidence after the trial court considers all evidence on both sides of the validity issue available at this early stage of the litigation." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372 , 1376 (Fed. Cir. 2009). To net that evidence, the court "must determine whether it is more likely than not that the [patent] challenger will be able to prove at trial, by clear and convincing evidence, that the patent is invalid." *Id*. at 1379.

[2] Defendants (at 10–11) cite *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253 (Fed. Cir. 2012), to argue "[a] court may afford greater weight to a prior art reference not considered by the PTO." *Sciele* involved only art omitted from prosecution, not a prior adjudication. The case is beside the point here.

[3] Novartis does not concede that Kappos 2006 was publicly available before June 27, 2006. The date stamp June 22, 2006 is for a "Document Supply Centre" that appears to be a warehouse without public access. Novartis reserves all rights for further discovery into this document. *In re Cronyn*, 890 F.2d 1158 (Fed. Cir. 1989).

argument rests on nothing more. (Def. Br. at 11 ("Kappos 2006 expressly discloses a Phase III clinical study comprising oral administration of daily doses of 0.5 mg of fingolimod to RRMS patients . . . . Nothing more is required to anticipate the asserted claims.").) Kappos 2006 accordingly should be disregarded. As for enablement and written description, those theories could not have been raised in the IPR, but fail for reasons shown below (at I.B.).

A. The Patent Claims Far More than Kappos 2006 Reveals

If the Court prefers to consider Kappos 2006 despite the IPR, the reference still fails to anticipate. Kappos 2006 neither enables nor discloses the claimed invention.

1. Kappos 2006 Discloses a Test, not an Enabled Method

Defendants agree only enabled references can anticipate. (Def. Br. at 15.) But defendants completely ignore the case Novartis's brief features (at 16), *GSK v. Glenmark*.

In *GSK*, plaintiff sought to enforce a method of treatment patent. Defendants argued "Kelly"—a prior announcement of a Phase III trial on the claimed method—anticipated. The argument was rejected at summary judgment and trial. Under *In re Montgomery*, 677 F.3d 1375 (Fed. Cir. 2012), Kelly's Phase III plan was simply too "theoretical" to be enabled. (*See* Nov. Br. at 16.) The parallels here are inescapable. Kelly indeed contained more enabling information than Kappos 2006—Kelly described positive Phase II results for the claimed method. Kappos 2006 does not. The 0.5 mg dose had never been tested before, as a person of skill would have understood when reading Kappos 2006. (*See* May 14, 2019 Second Declaration of Robert W. Trenchard Ex. 247 (Hoffman Dep. Tr.) at 180:7–181:14.)

The prior art here in fact taught away from 0.5 mg, as the Patent Office found and defendants do not dispute. (*See* Nov. Br. at 9.) Doctors in June 2006 were skeptical of even testing the dose in Phase III, much less actually using the dose to treat patients. (*See* D.I. 360

(Lublin Dec.) ¶¶ 59–84.) In these circumstances, the *Wands* factors point definitively away from Kappos 2006's enablement.[4] *See, e.g.*, *In re Hoffmann*, 558 F. App'x 985, 987 (Fed. Cir. 2014) (applying *Wands* factors to find no enablement when "the very efficacy of the method itself is subject to considerable doubt in the scientific community").[5]

Defendants (at 15) cite *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005), to assert "that in the context of a claimed method for treating a disease, a prior art reference need not disclose proof of efficacy to anticipate the claim." Nothing in *Rasmusson* conflicts with *GSK*; indeed, the Court cited *Rasmusson* in *GSK* but still found Kelly not enabled. *See GSK*, 2017 WL 8944995, at *19–21 (D. Del. May 2, 2017). Presumably, that is because the claims in *GSK* required using the method for a treatment purpose—a reference must enable the *claimed* invention to anticipate. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1345 (Fed. Cir. 2008) ("An anticipating reference must enable that which it is asserted to anticipate."); *GlaxoSmithKline LLC v. Glenmark Pharm., Inc.*, No. CV 14-877-LPS-CJB, 2016 WL 3186657, at *9 (D. Del. June 3, 2016), *report and recommendation adopted sub*

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[4] While not disputing teaching away, defendants say (at 13) a person of skill would not have doubted 0.5 mg daily for humans based on animal data. (*See infra*. at I.B.1.) A person of skill as defined by the Patent Office would consider animal data. As Dr. Lublin shows, an MS physician would take animal data seriously [redacted]. (Lublin Reply Dec. ¶¶ 12–14.)

In addition, defendants (at 14) cite *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998), to argue that "whether a reference 'teaches away' from the invention is inapplicable to an anticipation analysis[.]" *Celeritas* dealt only with whether teaching away could defeat an otherwise enabled and anticipatory reference. It is not relevant.

[5] Defendants complain (at 14) that Novartis relies on non-public documents to show skepticism. But defendants do not dispute this evidence corroborates what real persons of skill actually thought at the time. Courts routinely consider internal documents to assess that fact. *See, e.g., Bayer HealthCare LLC v. Baxalta Inc.*, 2018 WL 6727054, at *8 (D. Del. Dec. 21, 2018) (weighing internal confidential documents to assess person of skill's views).

nom., No. CV 14-877-LPS-CJB, 2017 WL 658468 (D. Del. Feb. 17, 2017). The Court found that Kelly did not enable a doctor to use the method as a treatment.

As in *GSK*, the Patent here claims a treatment purpose. That's what the Patent Office found. (D.I. 364 Ex. 73 at 14–15.) Kappos 2006 does not enable that purpose. It describes only a test—as Dr. Hoffman admitted, in June 2006 he would not have used 0.5 mg to treat a patient. (Ex. 247 (Hoffman Dep. Tr.) at 221:12–222:13; Lublin Reply Dec. ¶¶ 15–19.) While Novartis believes the claims further require some actual efficacy (*see* D.I. 426, Novartis's Claim Construction brief), that added meaning is not needed to find Kappos 2006 lacking enablement. Like Kelly in *GSK*, Kappos 2006 does not enable the claimed methods.[6]

2. The Patent Claims A Treatment, not a Test

A reference must also disclose all claimed elements to anticipate, as defendants agree (at 10). The 405 Patent claims a treatment—at minimum, that the drug be given for the purpose of treating RRMS, if not also to actually benefit some patients. (D.I. 426 at 16–18.) Kappos 2006 does not disclose a treatment. (Nov. Br. at 17–18.)

Dr. Hoffman argues otherwise based first on a single sentence in Kappos 2006 (D.I. 460 ¶ 85), which says the Phase II trial was a success but omits the doses tested. Dr. Hoffman seized on the missing doses to argue a person of skill would read Kappos 2006 to predict success for the planned Phase III doses, including 0.5 mg daily. But Dr. Hoffman backtracked in his deposition, admitting a person of skill would have known that 0.5 mg had never been

[6] *Rasmusson* may also have involved claims construed not to require efficacy. *Rasmusson* relies on *Bristol–Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368 (Fed. Cir. 2001). *BMS* involved claims construed to contain no efficacy element. While *Rasmusson* does not say how the claims in that case had been construed, if they were read not to require efficacy, as in *BMS*, then *Rasmusson* is even more off-point.

tested before. (Ex. 247 (Hoffman Dep. Tr.) at 180:7–181:14.) (And even if Dr. Hoffman had not conceded the point, the law presumes a person of skill would have been "aware of all the pertinent prior art." *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).) Dr. Hoffman thus agreed that a person of skill in June 2006—after Kappos 2006 was published—would never use the dose as a treatment; he "wouldn't know whether it was effective or not." Novartis's experts agree. (D.I. 360 (Lublin Dec.) ¶¶ 114–19; 359 (Steinman Dec.) ¶¶ 111–16; 361 (Jusko Dec.) ¶¶ 76–80.)

Defendants next seize on a sentence in Kappos 2006 describing the Phase III trial as an "intent to treat" study. (Def. Br. at 12; D.I. 460 (Hoffman Dec.) ¶ 83.) That phrase is just a statistical term of art. (Lublin Reply Dec. ¶¶ 20–21.) It means that the final results will be measured against the originally-enrolled population regardless of drop-outs. Given his lack of expertise, Dr. Hoffman simply misunderstood that term. (*Id.*) Dr. Hoffman indeed agreed study doctors could not have actually intended to treat patients. The study was double-blind and placebo controlled, so doctors would never know if they were giving a patient fingolimod or placebo. (Ex. 247, Hoffman Dep. Tr. 193:12–195:11; *see also* Lublin Reply Dec. ¶ 21.)

Defendants lastly argue (at 13–14) that Kappos 2006 "inherently" anticipates. As shown in Novartis's Opening Brief (at 17 n. 6), defendants' contentions state no inherency theory. That is dispositive. Novartis relied on defendants' contentions in addressing likelihood of success. A new invalidity theory now—after the time for opening expert reports has passed—would prejudice Novartis. *See, e.g.*, *Greatbatch Ltd. v. AVX Corporation*, 2015 WL 9690638 (D. Del. Jan. 5, 2015) (precluding arguments not disclosed by invalidity contentions).

In any event, Novartis showed (at 17 n. 6) that inherent anticipation is a non-starter. Under *In re Montgomery*, clinical trial results identified after the priority date cannot be used

to show inherency in the prior announcement of that trial. *See* 677 F.3d at 1378 (the clinical trial "results were not published until after Montgomery's priority date and thus are irrelevant to an anticipation analysis"). Any other result would transform a mere invitation to investigate into an anticipatory reference. *Id*. For that reason, inherency in *In re Montgomery* (and in *GSK*) was based on pre-priority date information. (*Id.* at 1382; *GSK*, 2017 WL 8944995 at *2.) But defendants' inherency argument relies on exactly what *In re Montgomery* says is improper. (Lublin Reply Dec. ¶ 23.) Defendants do not argue otherwise.

3. The Patent Excludes a Loading Dose that Kappos 2006 Does Not

Another claimed element missing from Kappos 2006 is the loading dose exclusion. (Nov. Br. at 17–18.) Dr. Hoffman agrees that Kappos 2006 says nothing about loading doses. (D.I. 460 (Hoffman Dec.) ¶ 80.) Defendants therefore must show that Kappos 2006 inherently discloses no loading dose. To prove that, defendants must show that Kappos 2006 "necessarily" precludes such a dose. (Nov. Br. at 18; Def. Br. at 4.) Defendants purport to make that showing based on two theories, neither of which withstands scrutiny.

First, defendants argue (at 9) Novartis is "judicially estopped" from disputing that Kappos 2006 precludes a loading dose, because Novartis argued in the IPR that the 405 Patent specification precludes a loading dose. Yet for judicial estoppel to apply, "the party to be estopped must have taken two positions that are irreconcilably inconsistent." *Port Erie Plastics, Inc. v. Uptown Nails, LLC*, 173 F. App'x 123, 126 (3d Cir. 2006); *New Hampshire v. Maine*, 532 U.S. 742, 743 (2001) ("a party's later position must be clearly inconsistent with its earlier position."). Novartis's arguments are entirely consistent.

The Patent specification provides a comprehensive dosing regimen. So when it describes a 0.5 mg "daily" dose, a person of skill reads "daily" to mean once a day, nothing

more. But Kappos 2006 is just a short abstract. Dr. Hoffman admitted when deposed that abstracts are highly summary, subject to word limits, and thus must leave out copious detail. (Ex. 247 (Hoffman Dep. Tr.) 191:3–193:3.) A person of skill thus would know that Kappos 2006's description of a "daily" dose would not necessarily preclude a loading dose. As Dr. Lublin testified, a person of skill would read Kappos 2006 and "know what they don't know." (D.I. 461 Ex. 62 (Lublin Dep. Tr.) 178:7–179:5.) Simply put, the different contexts mean persons of skill would read the different documents differently. (D.I. 360 (Lublin Dec.) ¶¶ 120–25; 361 (Jusko Dec.) ¶¶ 119–24.)

Second, defendants rely on Dr. Hoffman's declaration. (Def. Br. at 6.) But Dr. Hoffman never says Kappos 2006 "necessarily" precludes a loading dose. He at most suggests a person of skill would view a loading dose as unlikely. (D.I. 460 (Hoffman Dec.) ¶¶ 80–82.) That is not enough—probabilities and possibilities do not suffice. (Nov. Br. at 18.) In any event, Dr. Hoffman is not qualified to testify on loading doses here. Among other things, he did not even know fingolimod *had* been administered with a loading dose in transplant studies. (Ex. 247 (Hoffman Dep. Tr.) 223:5–9; *see also* D.I. 360 (Lublin Dec.) ¶ 124.)

B. A Person of Skill Would Read the Patent to Enable and Describe the Invention

The Patent Office defined a person of skill for the Patent as a team consisting of an MS physician or researcher, plus a pharmacologist. Novartis showed that this person would read the Patent's animal data and prophetic human example to enable and describe the invention. (Nov. Br. at 22–23.) Defendants argue otherwise by first trying to lower the level of skill to an MS physician alone, with no pharmacologist. That less-sophisticated person supposedly

would not read the Patent's animal data to enable the claims. Defendants contend also that the type of animal data in the Patent is insufficient. (Def. Br. 16–21.) Neither theory works.

1. A Person of Skill Is a Team With a Pharmacologist

Failure to analyze a patent from the perspective of the correct person of skill can be reversible error. *See Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1259 (Fed. Cir. 2007) (reversing patent judgment for failure to consider testimony from a correct person of skill). Given that, defendants' complete failure to apply the well-recognized law on how to define a person of skill is glaring. Defendants rely solely on a few conclusory sentences in Dr. Hoffman's declaration for their position. (D.I. 460 (Hoffman Dec.) ¶ 34.)

Under *Environmental Designs, Ltd. V. Union Oil Co.*, 713 F.2d 693, 696–97 (Fed. Cir. 1983), courts weigh many factors to decide level of skill in the art. No one factor is dispositive, and not every factor applies, but relevant here confirm the Patent Office's definition:

a. "type of problems encountered in the art": Dr. Hoffman agrees that the Patent concerns the field of drug dosing. (Ex. 247 (Hoffman Dep. Tr.) at 153:19–21.) He agrees also that an FDA Release on which he relied says pharmacologists are important to addressing drug dosing problems. (*Id.* at 235:3–17.) That makes sense—as Dr. Jusko shows, pharmacologists are experts in the pharmacokinetic (PK) and pharmacodynamic (PD) properties of drugs, fields integral to dose development. (D.I. 361 ¶¶ 18–26.) Dr. Lublin agrees. (D.I. 360 ¶¶ 96–102.)

b. "prior art solutions to those problems": Dr. Hoffman agrees that prior art on the Patent's face includes pharmacological analyses. (Ex. 247 (Hoffman Dep. Tr.) at 153:22–156:12.) As Drs. Lublin and Jusko show, these references apply PK and PD principles to develop doses for human use. (D.I. 360 (Lublin Dec.) ¶ 101; 361 (Jusko Dec.) ¶¶ 35–71.) Their testimony is unrebutted.

c. "sophistication of the technology": Dr. Hoffman agrees that drug development relies on pharmacology throughout the entire process, as the FDA Release confirms. The Release describes the sophisticated modeling techniques pharmacologists use to develop doses, as does the prior art. (D.I. 461 Ex. 3 at 66115–16; Lublin Reply Dec. ¶¶ 4–11.) Dr. Hoffman himself admitted that a pharmacologist would be needed to appreciate the connection between the Patent's animal data and human dose. (Ex. 247 (Hoffman Dep. Tr.) at 271:17–272:15.)

d. "educational level of active workers in the field": Dr. Hoffman agrees that people involved in drug dosing include pharmacologists with different backgrounds than physicians. As Dr. Lublin points out, authors on prior art papers specific to fingolimod included Novartis pharmacologists. (D.I. 360 (Lublin Dec.) ¶ 98.) These are the active workers in the field of drug dosing design.

Defendants' and Dr. Hoffman's only bases for disputing the level of skill are that (1) pharmacology allegedly is unnecessary to understand the Patent's claims, and (2) requiring a pharmacologist would exclude physicians with no access to a pharmacologist. (*Id.* ¶ 34.) But the ability to understand the claim language is not a factor in the analysis, and requiring pharmacology expertise is demanded by the science involved.

2. The "EAE" Animal Data in the Patent Enables and Describes the Invention

The Patent specification describes the inventors' EAE rat experiments and a prophetic human use of 0.5 mg daily for RRMS. (D.I. 364 Ex. 1 at 10:32–11:19.) Nothing more is needed to enable and describe the invention. (Nov. Br. at 22–23.)

Defendants, however, argue (at 18) that EAE is insufficient. EAE models sometimes show efficacy that does not translate to humans. True, but irrelevant. Defendants ignore the many prior art EAE studies of fingolimod specifically, which corresponded closely to results in humans. (*See* studies listed in D.I. 359 (Steinman Dec.) ¶¶ 70–90; 361 (Jusko Dec.) ¶¶ 59–71.) EAE tests had thus already proven highly correlative with human results for fingolimod.

In any event, the law does not require perfect symmetry between animal studies and human claims. A "reasonable" correlation suffices. (Nov. Br. at 22.) Defendants do not contend otherwise. And Dr. Hoffman admitted that EAE is the dominant animal model used to study RRMS (even if he personally has no experience with EAE RRMS systems). (Ex. 247 (Hoffman Dep. Tr.) at 178:15-21.) Dr. Hoffman further admitted the EAE experiment here could never have been done in humans, as the experiment required the animals' sacrifice. (*Id.* at 218:15–23.) That is exactly where only animal studies can enable a claim to a human use.

Defendants complain (at 18–19) that the Patent does not explain how to translate the EAE results into a human dose. This is a red herring. There is no need to show how to translate from an EAE dose to a human dose. The specification identifies the human dose of 0.5 mg daily. That's enough. Moreover, Dr. Jusko testified that a pharmacologist would easily understand how the EAE studies relate to the stated human doses. (D.I. 361 (Jusko Dec.) ¶¶ 186–88.) As above (at 10), Dr. Hoffman admits that a pharmacologist would have exactly such expertise. Dr. Steinman, too, says he would understand. (D.I. 359 (Steinman Dec.) ¶¶ 177–79.) A specification "need not teach, and preferably omits, what is well known in the art." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986).

II. Novartis Will Suffer Irreparable Injury Without an Injunction

If defendants are permitted to launch at risk, Novartis will suffer irreversible harm. Gilenya's unique market makes the harm unavoidable, even if defendants later left the market. Steep and irreversible price erosion, long-term loss of market share, disruption to newer MS drugs, and harm to goodwill will all result. (Nov. Br. at 24–30.) Long-term harms like these are exceedingly difficult to remedy with money damages, and thus well-recognized forms of irreparable injury. (*Id.*; *See, e.g.*, *Cipla Ltd. v. Amgen, Inc.*, No. CV 19-44-LPS, 2019 WL 1970780, at *14 (D. Del. May 2, 2019) ("irreversible price erosion [and] long-term loss of market share" are irreparable harm).)

Defendants first respond (at 22–23) not on the merits, but by accusing Novartis of delay in bringing this case. Novartis did not delay. Novartis held off while the Patent was being litigated in the Patent Office, and sued promptly after prevailing. (Waibel Dec. ¶¶ 1–10.) Delay counts against irreparable harm only if probative of a lack of concern for the harm. *Pfizer, Inc. v. Teva Pharm., USA, Inc.*, 429 F.3d 1364, 1381–82 (Fed. Cir. 2005) (finding that patent owner did not delay where there was "no immediate need . . . to sue"); *Integra Lifesciences Corp. v. Hyperbranch Med. Tech., Inc.*, No. CV 15-819-LPS-CJB, 2016 WL 4770244, at *9 (D. Del. Aug. 12, 2016) (finding no significant delay had occurred where there was not yet infringement). Novartis sued immediately after the IPR and more than a year before the generics could launch. Defendants cite no case and Novartis is aware of none where that sort of prompt action constitutes a delay weighing against irreparable injury. If the generics had wanted to litigate earlier, they were free to bring suit themselves. 35 U.S.C. 271(e)(5).

Defendants next respond (at 23–26) with generalized assertions that in some cases *past* price erosion and lost market share can be calculated and addressed with money damages.

Defendants never address the specific *long-term* harms here. Their expert Mr. Hofmann admitted the risk of these long-term harms when deposed, but says they are calculable. But that is mere assertion on his part—he points to no evidence or calculation in support. The evidence all points the other way.

Price Erosion: [redacted] price erosion will be steep and immediate after a launch at risk—[redacted] off of the current Gilenya price within a few months. (D.I. 363 (Vellturo Dec.) ¶ 61; Vellturo Reply Dec. ¶¶ 11–17.) A launch at risk likely would also force down the prices of the other branded oral RRMS medications. (D.I. 363 (Vellturo Dec.) ¶ 71.) Dr. Vellturo testified that this dynamic would make it unlikely that Novartis could restore the current price. (*Id*. ¶¶ 72–73; *See also* Vellturo Reply Dec. ¶¶ 7–8, 18–24, 39–54, 76–80.)

Mr. Hofmann did not even try to show otherwise (D.I. 459 (Hofmann Dec.) at ¶¶ 39–42), and conceded at his deposition that (1) price competition among the three oral drugs exists; (2) generic fingolimod could depress prices for other orals; and (3) these lower prices could persist and prevent Novartis from re-establishing the current price for Gilenya even if generics left the market. (Ex. 248 (Hofmann Tr.) at 133:3–23, 200:12–20, 203:7–204:12.) Although he claimed damages could remedy this price erosion, he never explained how in his declaration or deposition. (*Id*. at 204:14–205:17.) To the contrary, he suggested that modeling the future in this market would be difficult, a point only further compelling a finding that harm is irreparable. (*Id*. at 204:21–205:3; Vellturo Reply Dec. ¶¶ 1–3, 68-75.)

Defendants argue (at 23–25) that Novartis could avoid price erosion by choosing not to lower prices, or by launching an authorized generic. Neither argument makes any sense. Novartis cannot just ignore price decreases that reverberate across the market. (Vellturo Reply

Dec. ¶¶ 4–6, 18–24.) And an authorized generic (something Novartis has no plans for) would only exacerbate price erosion. (*Id*. ¶¶ 7–10.) Long-term price erosion is irrefutable.

Market Share Erosion. A launch at risk would likely cause long-term loss of market share, another classic form of irreparable harm. (Nov. Br. at 27–28.) A generic launch would [redacted] (D.I. 363 (Vellturo Dec.) ¶¶ 84–102.) Mr. Hofmann conceded that a launch at risk could cause [redacted] Defendants instead say Novartis could return "100%" to the same position in the market for *oral fingolimod* after generics left the market. (Def. Br. at 25–26.) That sidesteps Novartis's point, which is that Gilenya's share will shrink against *other drugs*. Mr. Hoffman conceded that patients might migrate to other branded drugs [redacted] (Ex. 248 (Hofmann Tr.) at 232:6–12.) He conceded also that he had done nothing to show how Novartis could calculate these damages. (*Id*. at 272:10–25.)[7]

Harm to New Products. A launch at risk would impair new MS product lines. Low cost generic Gilenya will depress prices for Mayzent, Novartis's newest MS drug. (Nov. Br. at 28–29.) As Dr. Vellturo explained, that disruption so early in Mayzent's life could have long term consequences difficult to model and capture in a damages theory. (D.I. 363 (Vellturo

[7] Mr. Hofmann says Novartis should [redacted] Dr. Vellturo explains that this strategy is not viable. (*Id*. ¶ 29.)

Dec.) ¶¶ 115–118; Vellturo Reply Dec. ¶¶ 60–67, 81–82.) Defendants do not rebut that showing. They do little more than point to internal Novartis documents that predict Mayzent will be successful, without addressing that this success will be diminished by a launch at risk.

Loss of Goodwill. A launch at risk threatens an incalculable loss of goodwill. MS physicians who rely on Novartis's patient support will suffer. (Nov. Br. at 29–30.) As Dr. Vellturo explained, and defendants do not contest, quantifying capturing these losses in a damages theory is virtually impossible. (D.I. 363 (Vellturo Dec.) ¶¶ 107–114; Vellturo Reply Dec. ¶¶ 55–59, 68–75.) Defendants do not address any of this case-specific evidence. Rather, in a section that appears to have been copy-pasted from another brief, defendants respond to points about a formulary position that Novartis never made. (Def. Br. at 26–27.)

III. The Balance of Equities and Public Interest Favor a Preliminary Injunction

A launch at risk would cause far more harm to Novartis than forbearing would to defendants. (Nov. Br. at 30.) Defendants do not dispute that point. [redacted].

Defendants instead argue that lower drug prices outweighs all harms. But courts usually find that lower drug prices are cancelled out by the risk to innovation from not enforcing patent rights. (*Id.*) Defendants do not dispute that point. With those considerations in equipoise, the unique harms to Novartis and patients here tip the balance of equities in favor of an injunction.

CONCLUSION

For the foregoing reasons and those stated in Novartis's Opening Brief and supporting papers, the Court should preliminarily enjoin the participating defendants from launching their ANDA products at risk.

Dated: May 14, 2019

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